

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:
Jonathan Fanger et al.

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For: DRILL GUIDE WITH ALIGNMENT FEATURE

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APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

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I. REAL PARTY IN INTEREST

The real party in interest is DePuy Spine, Inc., a Johnson & Johnson company. DePuy Spine, Inc. derives its rights in this application by virtue of an assignment of the application by Jonathan Fanger and Eric D. Kolb to DePuy Spine, Inc., recorded at Reel 014841, Frame 0389.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1, 3, 7, 11, 12, 16-19, 25-28, 33, 34, and 52-63 are currently pending in the present application, Serial Number 10/664,575. Claims 11, 12, and 26 are withdrawn. According to the final Office Action mailed on December 27, 2007, claims 1, 3, 7, 16-19, 25, 27, 28, 33, and 52-63 are rejected pursuant to 35 U.S.C. §102(b) as being unpatentable over U.S. Patent No. 5,423,826 of Coates et al.

Accordingly, claims 1, 3, 7, 16-19, 25, 27, 28, 33, and 52-63 are subject to appeal.

IV. STATUS OF AMENDMENTS

Appellants submitted an amendment in response to the final Office Action dated December 27, 2007 cancelling claim 63. The amendment was not entered. Accordingly, Appellants filed an amendment canceling claim 63 on April 25, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention generally provides guide devices to facilitate implantation of spinal implants during spinal surgery. Independent claim 1 recites a guide device, shown for example in FIG. 1 and described in paragraphs 0028-0036, for use with a spinal plate having at least one pair of screw bores formed therein that includes an elongate shaft (e.g., 12) having a proximal end and a distal end. A guide member (e.g., 18) coupled to the distal end of the elongate shaft includes first and second lumens (e.g., 20, 22) extending therethrough in fixed relation to one another. First and second opposed alignment tabs (e.g., 24, 26) extend distally from opposed outer edges of opposed ends of the guide member such that the first and second lumens are positioned between the first and second alignment tabs. (See Para. 0039). The first and second opposed alignment tabs are adapted to interact with a spinal plate to position the guide member with respect to the spinal plate such that the first and second

lumens in the guide member are aligned with a pair of corresponding screw bores formed in the spinal plate. (See Para. 0036).

Independent claim 28 recites a guide device for use with a spinal plate having at least one screw bore formed therein that includes an elongate shaft (e.g., 12) having a proximal end and a distal end, and a guide member (e.g., 18) coupled to the distal end of the elongate shaft and including first and second lumens (e.g., 20, 22) extending therethrough. First and second opposed alignment tabs (e.g., 24, 26) extend distally from opposed outer edges of opposed ends of the guide member such that at least one lumen is positioned between the first and second alignment tabs. The first and second opposed alignment tabs are adapted to non-fixedly interact with an edge of a spinal plate without engaging the spinal plate to position the guide member with respect to the spinal plate such that the first and second lumens in the guide member are aligned with at least one corresponding screw bore formed in the spinal plate. (See Para. 0036-0037).

Independent claim 52 recites a guide device for use with a spinal plate having at least one pair of screw bores formed therein, shown for example in Figures 5A-5B and described at paragraphs 0039-0040, that includes an elongate shaft having a proximal end and a distal end, and a guide member (e.g., 18') coupled to the distal end of the elongate shaft and including first and second lumens (e.g., 20', 22') extending therethrough in fixed relation to one another. At least one alignment tab (e.g., 24' or 26') extends distally from the guide member and is adapted to interact with a spinal plate to position the guide member with respect to the spinal plate such that the first and second lumens in the guide member are aligned with a pair of corresponding screw bores formed in the spinal plate. At least one protrusion (e.g., 40) extends distally from the guide member and is adapted to be disposed within a corresponding bore formed in the spinal plate. (See Para. 0040).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A. Whether the Examiner improperly rejected claims 1, 3, 7, 16-19, 25, 27, 28, 33, and 52-62 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,423,826 of Coates ("Coates").

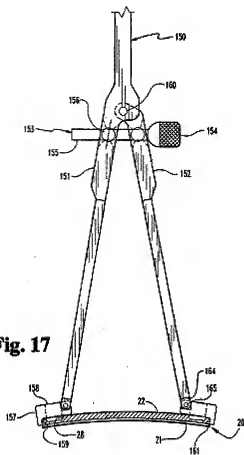
VII. ARGUMENT

A. Rejection Pursuant to 35 U.S.C. 102(b) Over Coates

1. *The Scope and Content of the Prior Art*

As shown in FIG. 17 of Coates, which is reproduced herein, Coates discloses a drill guide including two arms (151, 152) that are pivotally coupled to one another. The drill guide also includes a locking mechanism (153) having a threaded locking rod (155) that extends through and threadably mates to the arms (151, 152) such that rotation of the locking rod (155) pivots the arms. As the arms (151, 152) pivot with respect to one another, the distance between them at the pivot point remains relatively constant while the distance at the other end increases or decreases. Each arm (151, 152) includes a foot (157) with a thru-hole (158) extending therethrough that is used to engage with a bone plate (20). The feet (157) are pivotally coupled to the arms (151, 152) to accommodate various sized plates (20). Each foot (157) also includes a small hook (161) that is used to attach to a notch (159) on each end of the bone plate (20), and the locking mechanism (153) can be tightened to firmly attach the guide (150) to the plate (20).

Fig. 17



2. *The Examiner's Rejection*

Claims 1, 3, 7, 16-19, 25, 27, 28, 33, and 52-62 are rejected pursuant to 35 U.S.C. §102(b) as being unpatentable over U.S. Patent No. 5,423,826 of Coates et al. The Examiner argues that an elongate central portion of the device forms the claimed elongate shaft recited in independent claim 1, 28, and 52. The Examiner asserts that the feet (157) form the claimed guide member as the Examiner asserts that both feet (157) taken together are considered a single unit, and that the feet (157) are attached to the distal end of the shaft. The Examiner further asserts that the thru-holes (158) form the claimed lumens, and that they are positioned between hooks (161), which the Examiner asserts are the alignment tabs.

3. *Coates Does Not Teach The Claimed Invention*

a. **Independent Claim 1**

Independent claim 1 recites a guide device for use with a spinal plate that includes a guide member coupled to the distal end of the elongate shaft and having first and second lumens extending therethrough in fixed relation to one another. Coates fails to teach the claimed guide device.

As discussed above, Coates is directed to a drill guide including two arms (151, 152), each having a foot (157) with a thru-hole (158) extending therethrough. The Examiner argues that the feet and thru-holes are being considered as one unit and thus form the guide member and first and second lumens. The Examiner further argues that the two thru-holes of Coates are in *fixed relation* to one another, as required by claim 1.

The two separate elongate shafts (151, 152) of Coates cannot form the claimed elongate member and guide member. Each shaft is a separate component, and neither shaft has a guide member coupled thereto with two lumens. Instead, each shaft has a guide member with a single lumen formed therein. Claim 1 specifically requires a two-lumen guide member on the distal end of an elongate shaft – not two separate single lumen guide members on two separate shafts. This reason alone is sufficient to preclude Coates from anticipating claim 1.

Coates also fails to teach two lumens in fixed relation to one another, as further required by claim 1. First, the thru-holes (158) in the feet (157) of Coates' device are not in a fixed relation to one another because the feet (157) are pivotally coupled to the arms (151, 152). As a result of this pivotal movement between the feet (157) and the arms (151, 152), the thru-holes (158) are freely movable with respect to each other.

Second, the thru-holes (158) are not in a fixed relation to one another because the threaded locking rod (155) extends through and threadably mates to the arms (151, 152) such that rotation of the locking rod (155) using an adjustment knob (154) pivots the arms. As the arms (151, 152) pivot with respect to one another, the distance between the thru-holes (158) in the feet (157) increases or decreases. Thus, the thru-holes (158) extending through the feet of Coates are also not in a fixed relation to one another due to the pivotal movement of the arms (151, 152).

In the Advisory Action, the Examiner argues that “[w]hile the device may be adjustable, at some preferred setup and secured even if by the adjustment knob, they still provide a shaft with lumens fixed in relation to one another in the preferred setup.” While Appellants agree that at some point during the use of the device the arms (151, 152), the feet (157), and thus the thru-holes (158) will no longer be in motion, that is not the equivalent of the thru-holes (158) being in a fixed relation to one another. By this logic, any two objects could be considered in a fixed relationship as long as both of those objects are stationary during at least one moment in time. For example, using this argument, the Examiner and the Appellants’ representative would be in a fixed relation to one another if both the Examiner and the Appellants’ representative stood perfectly still at the same time, such as during a game of freeze-tag. Obviously, this argument is flawed in terms of what it means for something to be in a fixed relation to something else. Such an interpretation would render the limitation entirely meaningless.

Accordingly, claim 1, as well as claims 3, 7, 16-19, 25, and 27 which depend therefrom, distinguish over Coates and represent allowable subject matter.

b. Dependent Claim 3

Claim 3 depends from claim 1 and recites that the first and second opposed alignment tabs of claim 1 are adapted to non-fixedly interact with a spinal plate to align the guide member with the spinal plate. The Examiner asserts that the hooks (161) of Coates form the claimed alignment tabs. Column 13, lines 9-12 of Coates states that “[a] small hook 161 on each foot 157 of the guide attaches to a notch 159 on each end of the plate 20. The locking mechanism 153 is then tightened to firmly attach the guide 150 to the plate 20.” The hooks (161) clearly *engage* the notches to *firmly attach* the guide to the plate. Thus, the hooks cannot form the claimed alignment tabs that non-fixedly interact with a spinal plate. As explained in more detail herein with respect to independent claim 28, even if the locking mechanism is not tightened to firmly attach the hooks to the plate, the mere fact that the hooks can only interact with a plate by engaging notches in a plate would prevent the device of Coates from being capable of non-fixedly interacting with a plate, as required by claim 3. Accordingly, dependent claim 3 further distinguishes over Coates and represents allowable subject matter.

c. Dependent Claim 7

Claim 7 recites that the guide device includes at least one protrusion that extends distally from the guide member and that is adapted to be disposed within a corresponding bore formed in the spinal

plate. The only component of Coates that could be considered to extend from the feet (157) are the hooks (161), which the Examiner asserts form the claimed alignment tabs. Thus, the feet (157) do not include a protrusion, in addition to first and second alignment tabs, extending distally therefrom. Accordingly, dependent claim 7 further distinguishes over Coates and represents allowable subject matter.

d. Dependent Claim 18

Claim 18 recites that the guide member includes a first barrel having a lumen extending therethrough, and a second barrel having a lumen extending therethrough. Coates does not include any barrels with lumens extending therethrough. The feet (157) of Coates are plate-like and certainly would not be considered to be a barrel as required by claim 18. Accordingly, dependent claim 18 further distinguishes over Coates and represents allowable subject matter.

e. Independent Claim 28

Independent claim 28 recites a guide device having an elongate shaft with proximal and distal ends, and a guide member coupled to the distal end of the elongate shaft that includes first and second lumens extending therethrough. Claim 28 further recites first and second opposed alignment tabs extending distally from opposed outer edges of opposed ends of the guide member and adapted to non-fixedly interact with an edge of a spinal plate without engaging the spinal plate to position the guide member with respect to the spinal plate.

At the outset, as previously explained with respect to claim 1, Coates does not teach a two-lumen guide member coupled to a distal end of an elongate shaft. Instead, Coates teaches two separate single-lumen guide members mated to two separate elongate shafts. This basis alone is sufficient to preclude Coates from anticipating claim 28.

Coates also fails to teach first and second alignment tabs adapted to *non-fixedly* interact with an edge of a spinal plate *without engaging* the spinal plate. As previously explained with respect to claim 3, the hooks of Coates are not capable of non-fixedly interacting with a plate. The only way for the hooks to interact with a plate to align the holes in the feet with bores in the plate is for the hooks to extend into notches formed in the edge of a plate. Such a mating configuration will necessarily result in a fixed interaction, even if loosely fixed, because the plate cannot be detached from the feet, at least not

without disengaging the feet from the notches. Thus, Coates does not teach tabs that are adapted to non-fixedly interact with an edge of a spinal plate without engaging the spinal plate.

In the Advisory Action, the Examiner argues that “[e]ven though the hooks may “fixedly interact” this is not permanent. The Examiner seems to be misinterpreting the claim language. Appellants are not using the term fixed to mean permanent. The term is used to refer to the type of interaction, not whether the interaction is temporary or permanent. Coates specifically teaches that the hooks (161), with the use of the locking mechanism, cause the hooks to firmly attach to the plate. This is exactly what it means for the device to fixedly interact with a plate. This is contrary to non-fixedly interacting with the plate. For example, Appellants disclose tabs that extend from opposed sides of the guide member and can be positioned along edges of a spinal plate. As explained in Appellants’ specification in paragraph 0037:

While the tabs 24, 26 preferably do not rigidly engage the spinal plate, they can provide a clearance fit therebetween to prevent rotation of the guide member 18 with respect to the spinal plate when the tabs 24, 26 are aligned therewith. This is advantageous in that the tabs 24, 26 allow the guide member 18 to be quickly and easily positioned against, and subsequently removed from, the spinal plate.

Clearly, a non-fixed interaction is not equivalent to a fixed interaction just because both types of interaction are not permanent, as suggested by the Examiner.

Accordingly, independent claim 28, as well as claim 33 which depends therefrom, distinguishes over Coates and represents allowable subject matter.

f. Dependent Claim 33

Claim 33 recites that the guide member of claim 28 includes first and second barrels having the first and second lumens formed therein. As explained above with respect to claim 18, the feet (157) of Coates are not shaped like barrels and would not be considered to be barrels as this term is generally understood by a person having ordinary skill in the art. Accordingly, dependent claim 33 further distinguishes over Coates and represents allowable subject matter.

g. Independent claim 52

Independent claim 52 recites a guide device for use with a spinal plate that includes a guide member coupled to the distal end of the elongate shaft and having first and second lumens extending therethrough in fixed relation to one another. As explained above with respect to claim 1, Coates fails to teach a two-lumen guide member coupled to a distal end of an elongate shaft, much less a guide member having first and second lumens in *fixed* relation to one another. These reasons alone render claim 52 allowable over Coates.

In addition, claim 52 also recites at least one protrusion that extends distally from the guide member and that is adapted to be disposed within a corresponding bore formed in the spinal plate. The only component that extends in any way from the feet (157) of Coates are the hooks (161), which the Examiner asserts are the claimed alignment tabs. Thus, the feet (157) do not include a protrusion extending distally therefrom. The hooks (161) cannot form both the claimed protrusion and the claimed alignment tabs.

Accordingly, claim 52, as well as claims 53-62 which depend therefrom, distinguish over Coates and represent allowable subject matter.

h. Dependent Claim 54

Claim 54 recites that the at least one tab is adapted to non-fixedly interact with a spinal plate to align the guide member with the spinal plate. For reasons previously explained with respect to independent claim 28, Coates does not teach or even suggest tabs that are capable of non-fixedly interacting with a plate. Dependent claim 54 therefore distinguishes further over Coates and represents allowable subject matter.

i. Dependent Claim 56

Claim 56 recites that the at least one alignment tab includes an oval protrusion that extends distally from a distal end of the guide member. The hooks (161) of Coates are L-shaped, and thus cannot be considered to be an oval protrusion as required by claim 56. Accordingly, dependent claim 56 further distinguishes over Coates and represents allowable subject matter.

j. Dependent Claim 59

Claim 59 recites that the guide member includes a first barrel having the first lumen extending therethrough, and a second barrel having the second lumen extending therethrough. As explained above with respect to claim 18, the feet (157) of Coates are not shaped like barrels and cannot be considered to form barrels as this term is understood by a person having ordinary skill in the art. Accordingly, dependent claim 59 further distinguishes over Coates and represents allowable subject matter.

k. Dependent Claim 60

Claim 60 recites that the first and second barrels of claim 58 are positioned at an angle with respect to one another. As explained above, the feet (157) of Coates are not shaped like barrels. Thus, if there are no barrels, there necessarily can be no barrels that are positioned at an angle with respect to one another. Accordingly, dependent claim 60 further distinguishes over Coates and represents allowable subject matter.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,

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IX. APPENDIX A: CLAIMS ON APPEAL

1. (Previously Presented) A guide device for use with a spinal plate having at least one pair of screw bores formed therein, the guide device comprising:
 - an elongate shaft having a proximal end and a distal end;
 - a guide member coupled to the distal end of the elongate shaft and including first and second lumens extending therethrough in fixed relation to one another; and
 - first and second opposed alignment tabs extending distally from opposed outer edges of opposed ends of the guide member such that the first and second lumens are positioned between the first and second alignment tabs, the first and second opposed alignment tabs being adapted to interact with a spinal plate to position the guide member with respect to the spinal plate such that the first and second lumens in the guide member are aligned with a pair of corresponding screw bores formed in the spinal plate.
2. (Canceled)
3. (Previously Presented) The guide device of claim 1, wherein the first and second opposed alignment tabs are adapted to non-fixedly interact with a spinal plate to align the guide member with the spinal plate.
- 4-6. (Canceled).
7. (Previously Presented) The guide device of claim 1, further comprising at least one protrusion that extends distally from the guide member and that is adapted to be disposed within a corresponding bore formed in the spinal plate.
- 8-10. (Canceled).
11. (Withdrawn) The guide device of claim 1, wherein the guide member has a substantially rectangular, elongate shape and the first and second lumens extend therethrough.

12. (Withdrawn) The guide device of claim 11, wherein the guide member includes opposed superior and inferior sides and opposed transverse sides, the transverse sides having a width that is less than a width of the superior and inferior sides.

13-15. (Canceled).

16. (Original) The guide device of claim 1, wherein a distal surface of the guide member has a shape that conforms to the shape of a spinal plate.

17. (Original) The guide device of claim 1, wherein the first and second lumens are positioned at an angle with respect to one another.

18. (Original) The guide device of claim 1, wherein the guide member comprises a first barrel having a lumen extending therethrough, and a second barrel having a lumen extending therethrough.

19. (Original) The guide device of claim 18, wherein the first and second barrels are positioned at an angle with respect to one another.

20-24. (Canceled).

25. (Previously Presented) The guide device of claim 1, wherein the first and second alignment tabs are adapted to loosely interact with a spinal plate such that the guide member can pivot with respect to the spinal plate.

26. (Withdrawn) The guide device of claim 1, wherein the first and second lumens have an adjustable length.

27. (Original) The guide device of claim 1, wherein the proximal end on the elongate shaft is positioned at an angle with respect to a distal portion of the elongate shaft.

28. (Previously Presented) A guide device for use with a spinal plate having at least one screw bore formed therein, the guide device comprising:

an elongate shaft having a proximal end and a distal end; and
a guide member coupled to the distal end of the elongate shaft and including first and second lumens extending therethrough; and
first and second opposed alignment tabs extending distally from opposed outer edges of opposed ends of the guide member such that at least one lumen is positioned between the first and second alignment tabs, the first and second opposed alignment tabs being adapted to non-fixedly interact with an edge of a spinal plate without engaging the spinal plate to position the guide member with respect to the spinal plate such that the first and second lumens in the guide member are aligned with at least one corresponding screw bore formed in the spinal plate.

29-32. (Canceled).

33. (Previously Presented) The guide device of claim 28, wherein the guide member comprises first and second barrels having the first and second lumens formed therein.

34. (Withdrawn) The guide device of claim 33, wherein at least one of the first and second barrels has an adjustable trajectory such that the at least one barrel can pivot about a point on a longitudinal axis thereof.

35-51. (Canceled)

52. (Previously Presented) A guide device for use with a spinal plate having at least one pair of screw bores formed therein, the guide device comprising:

an elongate shaft having a proximal end and a distal end;
a guide member coupled to the distal end of the elongate shaft and including first and second lumens extending therethrough in fixed relation to one another;
at least one alignment tab extending distally from the guide member, the at least one alignment tab being adapted to interact with a spinal plate to position the guide member with respect to the spinal plate such that the first and second lumens in the guide member are aligned with a pair of corresponding screw bores formed in the spinal plate; and

at least one protrusion that extends distally from the guide member and that is adapted to be disposed within a corresponding bore formed in the spinal plate.

53. (Previously Presented) The guide device of claim 52, wherein the at least one alignment tab comprises first and second alignment tabs extending distally from opposed outer edges of opposed ends of the guide member.
54. (Previously Presented) The guide device of claim 52, wherein the at least one tab is adapted to non-fixedly interact with a spinal plate to align the guide member with the spinal plate.
55. (Previously Presented) The guide device of claim 52, wherein the at least one alignment tab is adapted to prevent rotation between the guide member and a spinal plate when the guide member is mated to a spinal plate.
56. (Previously Presented) The guide device of claim 55, wherein the at least one alignment tab comprises an oval protrusion that extends distally from a distal end of the guide member.
57. (Previously Presented) The guide device of claim 52, wherein a distal surface of the guide member has a shape that conforms to the shape of a spinal plate.
58. (Previously Presented) The guide device of claim 52, wherein the first and second lumens are positioned at an angle with respect to one another.
59. (Previously Presented) The guide device of claim 52, wherein the guide member comprises a first barrel having the first lumen extending therethrough, and a second barrel having the second lumen extending therethrough.
60. (Previously Presented) The guide device of claim 59, wherein the first and second barrels are positioned at an angle with respect to one another.
61. (Previously Presented) The guide device of claim 52, wherein the at least one alignment tab is adapted to loosely interact with a spinal plate such that the guide member can pivot with respect to the spinal plate.

62. (Previously Presented) The guide device of claim 52, wherein the proximal end on the elongate shaft is positioned at an angle with respect to a distal portion of the elongate shaft.

63. (Cancelled).

X. APPENDIX B: EVIDENCE

No evidence submitted.

XI. APPENDIX C: RELATED PROCEEDINGS

No related proceedings.

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